CONSUMER ACTION for a STRONG ECONOMY

April 3, 2019

Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone,

On behalf of millions of U.S. patients and consumers, our organization CASE writes to urge the Energy and Commerce Committee to implement H.R. 990, the Hatch-Waxman Integrity Act, as an amendment to H.R. 965, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. It is imperative that the American healthcare system allows for market competition, while protecting and encouraging future innovation. The Hatch-Waxman Integrity Act allows for both.

As the system stands, generic manufacturers are offered two pathways to challenge branded drug patents – the Hatch-Waxman framework and inter partes review (IPR). This "double jeopardy" challenge system opens innovators up to duplicative and unnecessary litigation costs, leading to a loss of innovator incentive and increased drug prices. Adopting H.R. 990 does not limit generic manufacturers from initiating patent challenges, but instead mandates they choose one pathway to preserve the progress of American healthcare.

The Hatch-Waxman Integrity Act is common-sense policy that eliminates frivolous repeat challenges, restores predictability for companies making multi-billion-dollar R&D investments, and boosts generic entry into the pharmaceutical market. We implore that the committee adopt this modest proposal to best serve the American people.

Sincerely,

Gerard Scimeca

Vice President, Consumer Action for a Strong Economy (CASE)